K090134

APR 21 2009

510(k) SUMMARY

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number:	1018223
Address of Manufacturer:	Bard Medical Division C. R. Bard, Inc. 8195 Industrial Blvd. Covington, Georgia 30014 USA Phone: (770) 784-6774 Fax: (770) 784-6340
Contact Person:	Scott Pease Senior Manager, Regulatory Affairs
Date Prepared:	April 2, 2009
Trade or Proprietary Name:	Intravenous Power Injector Extension Set
Common or Usual Name:	Set, Administration, Intravenous
Classification Name:	Intravascular administration set (21 CFR 880.5440) Product code: FPA Class II
Predicate Device Identification:	IV Administration Sets (extension set) with Needleless Access Device (K980992) SmartSite® Needle-Free Valve Administration Set (K061285)

Device Description:

The Intravenous Power Injector Extension Set is an IV extension set intended for the aspiration and/or delivery of fluids and may be used with power injectors having a maximum pressure setting of 325 psi and maximum flow rate of 10 ml/second.

The Intravenous Power Injector Extension Set consists of polyvinyl chloride (PVC) tubing with non-DEHP plasticizer, configured with a male luer with hex lock hub on its distal end and a female luer lock on its proximal end. A slide clamp is positioned over

the tubing to obstruct the fluid flow when needed by sliding the tubing into the narrow portion of the slide clamp.

The Intravenous Power Injector Extension Set is available in a configuration with and without a needle-free valve. The configuration with the valve allows access to the fluid delivery pathway without the use of a needle while maintaing a closed system for the fluid path. The valve is attached to the female luer lock.

The Intravenous Power Injector Extension Set is provided sterile for single use only. It is packaged with a commercially available skin protectant prep pad and a commercially available StatLock® stabilization device.

Intended Use

The Intravenous Power Injector Extension Set is intended to allow for the aspiration, injection or gravity/pump flow of fluids and may be used with low pressure power injectors having a maximum pressure setting of 325 psi and maximum flow rate of 10 ml/second. When used with a low pressure power injector, the Intravenous Power Injector Extension Set must be secured with other devices rated for pressures up to 325 psi with a luer lock connection.

Technological Characteristics and Comparison to Predicate Devices

The differences in technological characteristics (e.g., design specifications) between the subject and predicate devices do not raise new types of safety or effectiveness questions. Accepted scientific methods, such as performance (bench) testing, do exist for assessing the effect of the differences in characteristics.

Performance Data

The results of performance testing demonstrated that the functionality, integrity, and safety of the Intravenous Power Injector Extension Set are adequate for its intended use and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott Pease
Senior Manager, Regulatory Affairs
C.R. Bard, Incorporated
Bard Medical Division
8195 Industrial Boulevard
Covington, Georgia 30014

APR 21 2009

Re: K090134
Trade/Device Name: Intravenous Power Injector Extension Set
Regulation Number: 21 CFR 880.5440
Regulatory Class: II
Product Code: FPA
Dated: April 3, 2009
Received: April 6, 2009

Dear Mr. Pease:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090134 *(To be assigned by FDA)*

Device Name: Intravenous Power Injector Extension Set

Indications for Use:

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Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090134